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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
MOHAMED, ABDEL A	
ART UNIT	**PAPER NUMBER**
1653	

DATE MAILED: 05/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/010,715	PATHAK ET AL.	
	Examiner	Art Unit	
	Abdel A. Mohamed	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 June 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4,5,6*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

ACKNOWLEDGMENT OF IDS AND STATUS OF THE CLAIMS

1. The information disclosure statement (IDS) and Form PTO-1449 filed 3/7/02, 9/16/02 and 6/9/03 are acknowledged, entered and considered. Claims 1-35 are present for examination.

OBJECTION TO TRADEMARKS AND THEIR USE

2. The use of the trademarks "Pluronic®", "Tetronic®", and "Fibriject®" have been noted in this application. The trademarks have not been capitalized, they should be capitalized wherever they appear and be accompanied by the generic terminology. Although, the use of trademarks are permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in a manner, which might adversely affect their validity as trademarks.

Further, the specification, which specifies the generic terminology should include, published product information sufficient to show that the generic terminology or the generic description are inherent in the article referred by the trademarks. These description requirements are made because the nature and composition of articles denoted by trademarks can change and affect the adequacy of the disclosure.

CLAIMS REJECTION-35 U.S.C. § 103(a)

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-12 and 21-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hubbell et al. (U.S. Patent No. 5,410,016) taken with Rhee et al. (U.S. Patent No. 5,874,500) and Hsu et al. (U.S. Patent No. 5,192,743).

The Hubbell et al. patent discloses biocompatible, biodegradable water soluble polymerizable macromers containing polymeric component, a biodegradable component, and a protein reactive functional component having a variety of uses *in vivo.* The macromers include at least one water soluble region, at least one region which is biodegradable, usually by hydrolysis, and at least two free radical-polymerizable regions, wherein the macromers are polymerized by exposure of the

polymerizable regions to free radicals generated, for example, by photosensitive chemicals and dyes (See e.g., col. 4, lines 29 to col. 5, lines 14). The choice of the photoinitiator is largely dependent on the photopolymerizable regions. For example, when the macromere includes at least one carbon-carbon double bond, light absorption by the dye causes the dye to assume a triplet state, the triplet state subsequently reacting with the amine to from a free radical, which initiates polymerization. Preferred dyes for use with these materials include eosin dye and initiators such as 2,2-dimethyl-2-phenylacetophenone, 2-methoxy-2-phenylacetophenone, and camphorquinone. Using such initiators, copolymers may be polymerized *in situ* by long wavelength detectable to a human eye having ultraviolet range or visible range, 320 nm or higher, most preferably about 514 nm or 365 rim. The reference continues by stating that there are several photooxidizable and photoreducible dyes that may be used to initiate polymerization. These include acridine dyes, for example, acriblarine; thiazine dyes, for example, thionine; xanthine dyes, for example, rose Bengal; and phenazine dyes, for example, methylene blue as claimed in claims 9 and 27 (See e.g. col. 9, lines 20-63).

On col. 10, the '016 patent shows the applications for the macromers in which the preferred application is a reduction of the formation of adhesions after a surgical procedure in a patient, which includes coating damaged tissue surfaces in a patient with an aqueous solution of a light-sensitive free-radical polymerization initiator and a macromere solution. The second preferred application concerns a locally applying a biologically active substance or drug to tissue surface in a patient. Another use of the polymers is adhering tissue surface in a patient. The macromere is mixed with a

photoinitiator or photoinitiator/cocatalyst mixture to form an aqueous mixture and the mixture is applied to a tissue surface to which adhesion is desired. Thus, the reference clearly discloses a polymeric coating for a substrate comprising a hydrogel for on a substrate as a patient tissue. The hydrogel has water, a biocompatible visualization agent, and reactive hydrophilic polymers that form a crosslinked hydrogel after contact with the tissue. The hydrogel coats the tissue and forms a coating. The coating may have a free surface. The visualization agent is disposed in the hydrogel and reflects or emits light at a wavelength detectable to a human eye, and as such meets the limitations of claims 1, 2, 5, 8-10, 12 and 24-27. On col. 11, the reference demonstrates the polymeric coating of thickness of 1-500 microns. 500 microns is 0.5 mm because 1 mm is 1,000 microns. Thus, 0.5 mm is 500 microns, and as such it is within the claimed ranges of 0.1-10 mm (claim11).

The reference of Hubbell et al. differs from claims 1-12 and 21-27 in not teaching the use of crosslinked hydrophilic polymers having chemical crosslinks identifiable as products of an electrophilic functional group-nucleophilic functional group reaction, wherein the crosslinked hydrophilic polymers comprise polyethylene glycol and a hydrolytically biodegradable portion chosen from the group consisting of ester, amide, or carbonate linkage, and a kit formulation for making a hydrogel composition adapted for use with a tissue of a patient. However, Rhee et al. teach the employment of crosslinked polymer composition comprising a first synthetic polymer containing multiple nucleophilic groups covalently bound to a second synthetic polymer containing multiple electrophilic groups. The first synthetic polymer is preferably a synthetic polypeptide or

a polyethylene glycol that has been modified to contain multiple nucleophilic groups, such as primary amino (-NH_2) or thiol (-SH) groups. The second synthetic polymer may be a hydrophilic or a hydrophobic synthetic polymer which contains, or has been derivatized to contain, two or more electrophilic groups, such as succinimidyl groups. Also disclosed are employment of the crosslinked polymer compositions to effect adhesion between a first surface and a second surface; to effect tissue augmentation; to prevent the formation of surgical adhesions; and to coat a surface of synthetic implant (See e.g., abstract) as directed to claims 2, 4, 6-8 and 26. On col. 10, lines 63-67, the '500 patent states that the crosslinked polymer compositions may contain various imaging agents such as iodine or barium sulfate, or fluorine, in order to aid visualization of the composition. Thus, suggesting the use of various visualization agents including fluorine to improve visibility and performance in a surgical environment. On col. 13, lines 13 to 33, the reference suggests for use in tissue adhesion other than collagen or synthetic materials, it may also be desirable to incorporate proteins such as albumin, fibrin, or fibrinogen into the crosslinked polymer composition to promote cellular adhesion. Thus, meeting the limitations of claims 3 and 4. Further, on col. 15, lines 52-59, the reference states that incorporating biologically active agents containing nucleophilic groups into the crosslinked polymer composition involves mixing the active agent with the first synthetic polymer (or first synthetic polymer/collagen mixture) prior to adding the second synthetic polymer, which would result in covalent binding of the active agent to the crosslinked polymer composition, producing a highly effective sustained release composition. Thus, clearly showing the incorporation of biologically

active agent into a polymeric composition and as such meets the limitations of claims 12 and 23.

With respect to the kit, the reference of Hsu et al. teaches the use of multi-unit formulation package in a form of a kit containing a hydrolytically biodegradable protein, wherein the multi-unit formulation package comprises, in one unit, the lyophilized formulation before reconstitution, and in another unit, a diluent (reconstitution agent) for the formulation (See Summary of the Invention). Thus, from the cited references, one of ordinary skill in the art would have had the claimed kit(s) and compositions(s) based upon the teachings of the combined references as set forth in claims 21-23. The combined references teach using these compositions together in the same formulation that would have been found in the claimed composition and/or kits to formulate composition into a kit format because the claimed kit is tailored for use in the claimed kit formulation comprising the composition claimed. Hence, it would have been obvious to package the composition required for the method into kit format of the well-known commercial expediency of doing so.

Therefore, the combined teachings of the prior art makes obvious the claimed invention because at the time the invention was made based on the combined teachings of prior art and for the reasons given above; one of ordinary skill in the art would apply the composition(s) disclosed by the primary reference of '016 patent with the secondary references of '500 and '743 patents to employ a hydrogel for use on a substrate as a patient tissue. The hydrogel has water, a biocompatible visualization agent, and reactive hydrophilic polymers that form a crosslinked hydrogel after contact

with the tissue. The hydrogel coats the tissue and forms a coating. The coating may have a free surface. The visualization agent is disposed in the hydrogel and reflects or emits light at a wavelength detectable to a human eye, and a kit formulation thereof. Because of the teachings of the prior art, the first and second polymer precursors have to be mutually reactive, it would have been obvious to one of ordinary skill in the art to combine an electrophilic crosslinker with a nucleophilic polymer and a nucleophilic crosslinker with an electrophilic polymer, and one of ordinary skill in the art would have a reasonable expectation that the composition claimed in the instant application would be successful. Thus, in view of the above and the combined teachings of the prior art, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, absent of sufficient objective factual evidence or unexpected results to the contrary.

4. Claims 13-20 and 28-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hubbell et al. (U.S. Patent No. 5,410,016) taken with Rhee et al. (U.S. Patent No. 5,874,500).

The Hubbell et al. patent discloses a method of preparing a composition suitable to coat a tissue of a patient comprising biocompatible, biodegradable water soluble polymerizable macromers containing polymeric component, a biodegradable component, and a protein reactive functional component having a variety of uses *in vivo.* The macromers include at least one water soluble region, at least one region which is biodegradable, usually by hydrolysis, and at least two free radical-

polymerizable regions, wherein the macromers are polymerized by exposure of the polymerizable regions to free radicals generated, for example, by photosensitive chemicals and dyes. The '016 patent also discloses the macromere backbone is formed of a nondegradbale backbone having water soluble regions as branches or grafts attached to the degradable backbone. Two or more polymerizable regions are attached to the water soluble branches or grafts. Thus, the crosslinking agent is linear or branched and comprises a plurality of branches, wherein said plurality is greater than two and the inert component is flanked at each end with biodegradable component which is flanked at each end with a protein reactive functional component (See e.g., col. 4, lines 29 to col. 5, lines 14). Further, on col. 9, lines 20-63, the reference states that useful photoinitiators are those which can be used to initiate by free radical generation polymerization of the macromers without cytotoxicity and within a short time frame, minutes at most and most preferably seconds, which reads within 60 seconds or 5 seconds as directed to claims 14, 33 and 15, respectively. The choice of the photoinitiator is largely dependent on the photopolymerizable regions. For example, when the macromere includes at least one carbon-carbon double bond, light absorption by the dye causes the dye to assume a triplet state, the triplet state subsequently reacting with the amine to form a free radical, which initiates polymerization. Using such initiators, copolymers may be polymerized *in situ* by long wavelength detectable to a human eye having ultraviolet range or visible range, 320 nm or higher, most preferably about 514 nm or 365 rim, and as such meet the limitation of claim 13.

On col. 10, the '016 patent shows the applications for the macromers in which the preferred application is a method of reducing formation of adhesions after a surgical procedure in a patient. The method includes coating damaged tissue surfaces in a patient with an aqueous solution of a light-sensitive free-radical polymerization initiator and a macromere solution. The second preferred application concerns a method of locally applying a biologically active substance or drug to tissue surface in a patient. Another use of the polymers is in a method for adhering tissue surface in a patient. The macromere is mixed with a photoinitiator or photoinitiator/cocatalyst mixture to form an aqueous mixture and the mixture is applied to a tissue surface to which adhesion is desired. Thus, the reference clearly discloses a polymeric coating for a substrate comprising a hydrogel for on a substrate as a patient tissue. The hydrogel has water, a biocompatible visualization agent, and reactive hydrophilic polymers that form a crosslinked hydrogel after contact with the tissue. The hydrogel coats the tissue and forms a coating. The coating may have a free surface. The visualization agent is disposed in the hydrogel and reflects or emits light at a wavelength detectable to a human eye, and as such meets the limitations of claims 13-16, 19, 30, 31, and 33-35.

On col. 11, the reference demonstrates the polymeric coating of thickness of 1-500 microns. 500 microns is 0.5 mm because 1 mm is 1,000 microns. Thus, 0.5 mm is 500 microns, and as such it is within the claimed ranges of 0.1-10 mm (claim 29) or 0.5 to 4.0 mm (claim 18). Thus, the disclosed polymeric coating thickness of the reference overlaps with the claimed thickness, and as such, meets the limitations of claims 17, 18, 28 and 29.

The reference of Hubbell et al. differs from claims 13-20 and 28-35 in not teaching the use of crosslinked hydrophilic polymers having chemical crosslinks identifiable as products of an electrophilic functional group-nucleophilic functional group reaction, wherein the crosslinked hydrophilic polymers comprise polyethylene glycol and a hydrolytically biodegradable portion chosen from the group consisting of ester, amide, or carbonate linkage. However, Rhee et al. teach the employment of crosslinked polymer composition comprising a first synthetic polymer containing multiple nucleophilic groups covalently bound to a second synthetic polymer containing multiple electrophilic groups. The first synthetic polymer is preferably a synthetic polypeptide or a polyethylene glycol that has been modified to contain multiple nucleophilic groups, such as primary amino ($-NH_2$) or thiol (-SH) groups. The second synthetic polymer may be a hydrophilic or a hydrophobic synthetic polymer which contains, or has been derivatized to contain, two or more electrophilic groups, such as succinimidyl groups. Also disclosed are methods for using the crosslinked polymer compositions to effect adhesion between a first surface and a second surface; to effect tissue augmentation; to prevent the formation of surgical adhesions; and to coat a surface of synthetic implant (See e.g., abstract) as directed to claims 16 and 32. On col. 10, lines 63-67, the '500 patent states that the crosslinked polymer compositions can also be prepared to contain various imaging agents such as iodine or barium sulfate, or fluorine, in order to aid visualization of the composition. Thus, suggesting the use of various visualization agents including fluorine to improve visibility and performance in a surgical environment. Further, on col. 15, lines 52-59, the reference states that a simple method for

incorporating biologically active agents containing nucleophilic groups into the crosslinked polymer composition involves mixing the active agent with the first synthetic polymer (or first synthetic polymer/collagen mixture) prior to adding the second synthetic polymer. This procedure will result in covalent binding of the active agent to the crosslinked polymer composition, producing a highly effective sustained release composition. Thus, clearly showing the incorporation of biologically active agent into a polymeric composition and as such meets the limitations of claim 35.

In regard to claim 20, the claim is in product-by-process format. The novelty and patentability of the claimed product is based on the claimed procedure and not on the recited process steps. Claim 20 recites (even as dependent on claim 16) no new novel properties based on the claim 16 recited process. The cited combined references teach that the old product have been expected by one of ordinary skill in the art to have been adherent (See e.g., col. 10, lines 50-56 of '016 patent which teaches a method for adhering tissue surface in a patient by mixing the macromer with a photoinitiator or photoiniator/cocatalyst mixture to form an aqueous mixture and the mixture is applied to a tissue surface to which adhesion is desired).

Therefore, the combined teachings of the prior art makes obvious the claimed invention because at the time the invention was made based on the combined teachings of prior art and for the reasons given above; one of ordinary skill in the art would apply the methods disclosed by the primary reference of '016 patent with the secondary references of '500 and '743 patents to prepare a hydrogel for use on a substrate as a patient tissue. The hydrogel has water, a biocompatible visualization

agent, and reactive hydrophilic polymers that form a crosslinked hydrogel after contact with the tissue. The hydrogel coats the tissue and forms a coating. The coating may have a free surface. The visualization agent is disposed in the hydrogel and reflects or emits light at a wavelength detectable to a human eye, and a method for formulating a polymer composition thereof. Because of the teachings of the prior art, the first and second polymer precursors have to be mutually reactive, it would have been obvious to one of ordinary skill in the art to combine an electrophilic crosslinker with a nucleophilic polymer and a nucleophilic crosslinker with an electrophilic polymer, and one of ordinary skill in the art would have a reasonable expectation that the method claimed in the instant application would be successful. Thus, in view of the above and the combined teachings of the prior art, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, absent of sufficient objective factual evidence or unexpected results to the contrary.

HEADING FOR NONSTATUTORY DOUBLE PATENTING

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

OBVIOUSNESS-TYPE DOUBLE PATENTING

6. Claims 1-35 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-27 of U.S. Patent No. 6,566,406 in view of U.S. Patent No. 5,410,016 and U.S. Patent No. 5,192,743. Although, the conflicting claims are not identical, they are not patentably distinct from each other because the instantly claimed invention (Serial No. 10/010,715) as claimed in claims 1-20 and 24-35 is directed to biocompatible crosslinked polymers, and methods for their preparation and use in which the biocompatible crosslinked polymers containing visualization agents are formed from water soluble precursors having electrophilic and nucleophilic functional groups capable of reacting and crosslinking *in situ*. The instant application further claims the use of a kit formulation thereof (See e.g., claims 21-23). Similarly, the claims of U.S. Patent No. 6,566,406 is directed to biocompatible crosslinked polymers, and methods for their preparation and use in which the biocompatible crosslinked polymers are formed from water soluble precursors

having electrophilic and nucleophilic groups capable of reacting and crosslinking *in situ* (See e.g., claims 1-27 of '406 patent).

Further, both inventions use the same procedure/process for preparing a biocompatible crosslinked hydrogel (See e.g., the method of claims 13 and 28 of the instant invention are substantially the same as claims 1 and 12 of '406 patent, respectively) and use substantially the same composition/formulation i.e. a biocompatible crosslinked polymer hydrogel for the same purpose (See e.g., claim 19 of '406 patent is substantially the same as claims 1 and 24 of the instant application). The difference between the two inventions is the instant invention claims use of visualization agent that reflects or emits light at wavelength detectable to a human eye and a kit formulation thereof. However, the '016 patent on col. 10, discloses the use of a polymeric coating for a substrate comprising a hydrogel for on a substrate as a patient tissue. The hydrogel has water, a biocompatible visualization agent, and reactive hydrophilic polymers that form a crosslinked hydrogel after contact with the tissue. The hydrogel coats the tissue and forms a coating. The coating may have a free surface. The visualization agent is disposed in the hydrogel and reflects or emits light at a wavelength detectable to a human eye, and as such meets the limitations of claims 1, 2, 5, 8-10, 12-16, 19, 24-27, 30, 31 and 33-35.

With respect to the kit, the '743 patent teaches the use of multi-unit formulation package in a form of a kit containing a hydrolytically biodegradable protein, wherein the multi-unit formulation package comprises, in one unit, the lyophilized formulation before reconstitution, and in another unit, a diluent (reconstitution agent) for the formulation

(See Summary of the Invention). Thus, from the cited references, one of ordinary skill in the art would have had the claimed kit(s) and compositions(s) based upon the teachings of the combined references as set forth in claims 21-23. The combined references teach using these compositions together in the same formulation that would have been found in the claimed composition and/or kits to formulate composition into a kit format because the claimed kit is tailored for use in the claimed kit formulation comprising the composition claimed. Hence, it would have been obvious to package the composition required for the method into kit format of the well-known commercial expediency of doing so.

Therefore, the subject matter claimed in the instant application is set forth in '406 patent claims in view of the prior art cited therewith. Hence, it is within the purview of one of ordinary skill in the art to which this invention pertains to easily adapt the claimed biocompatible crosslinked polymers, and methods for their preparation and use in which the biocompatible crosslinked polymers containing visualization agents are formed from water soluble precursors having electrophilic and nucleophilic functional groups capable of reacting and crosslinking *in situ*, and the use of a kit formulation thereof since both sets of inventions use substantially the same method for preparing a biocompatible crosslinked polymer hydrogel and composition thereof for the same purpose. Therefore, one of ordinary skill in the art would envision both sets of claims as one invention.

CONCLUSION AND FUTURE CORRSPONDANCE

7. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abdel A. Mohamed whose telephone number is (571) 272-0955. The examiner can normally be reached on Monday through Friday from 7:30 a.m. to 5:00 p.m. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher S.F. Low can be reached on (571) 272-0951. The appropriate fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306 for regular communications and (703) 305-7401 for After Final communications..

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Mohamed/AAM

May 6, 2004